

FDA CDRH DMC

K/02/50

SIEMENS

JUL 29 2010 Healthcare

Received

510(k) Summary

OCT - 5 2010

syngo® Dynamics (version 9.0)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

1. General Information

Date of Summary Preparation: July 12, 2010
Address: Siemens Medical Solutions USA, Inc.
400 W. Morgan Road
Ann Arbor, MI 48108
Registration Number: 1836549
Contact Person: Ms. Yuri Ikeda
Quality Engineer, Quality & Regulatory
Phone: (734) 205-2442
Fax: (734) 205-2683
Email: yuri.ikeda@siemens.com

2. Device Name and Classification

Trade Name: syngo® Dynamics
Version 9.0
Classification Name: Picture Archiving and Communications System
Classification Panel: Radiology
CFR Number: 21 CFR §892.2050
Device Class: Class II
Product Code: LLZ

3. Substantial Equivalence

The syngo® Dynamics version 9.0, addressed in this premarket modification is substantially equivalent to the following commercially available device:

Manufacturer	Predicate Device Name	FDA Clearance Number
Siemens	syngo Dynamics Version 7.0	K081018

4. Device Description

This premarket notification addresses the Siemens syngo® Dynamics version 9.0 Picture Archiving and Communication System.

syngo® Dynamics is intended to display, process, read, report, communicate, distribute and store digital medical images. The system is a "software only" medical device. It defines recommended requirements to the hardware it runs on.

Siemens Medical Solutions USA, Inc.

400 West Morgan Road
Ann Arbor, MI 48108
USA

Tel.: +1-734-205-2400
www.usa.siemens.com/healthcare

3-1

The hardware itself is not considered a medical device and not in the scope of this 510(k) submission.

syngo® Dynamics supports the physician in diagnosis and treatment planning. It also supports storage and archiving of DICOM Structured Reports. In a comprehensive imaging suite *syngo*® Dynamics integrates Hospital / Radiology / Cardiology Information Systems (HIS/RIS/CIS) to enable customer specific workflows.

The *syngo*® Dynamics new release focuses on support of web based reporting. Also, in *syngo*® Dynamics 9.0, server as well as the workplaces will be offered as "software-only".

5. Intended Use

syngo® Dynamics is a Picture Archiving and Communication System (PACS) intended for acceptance, transfer, display, storage, archive and manipulation of digital medical images, including quantification and report generation.

syngo® Dynamics is not intended to be used for reading of mammography images.

6. Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device

syngo® Dynamics version 9.0 has been modified to add capability for web based reporting as well as providing a complete "software only" solution. *syngo*® Dynamics version 9.0 has the same intended use and the same fundamental scientific technology as the predicate device.

7. General Safety and Effectiveness Concerns

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of this device.

Risk management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing.

Siemens Medical Solutions USA, Inc. complies with voluntary standards DICOM Version 3.0, IEC/ISO 10918-1:1994 (JPEG), SMPTE RP 133-1991, ISO 14971:2007, IEC 62304:2006, HL7 Version 2.x, IEC 60601-1-4:2000, and IEC 60601-1-6:2006. Software Unit, Integration and System Testing are performed for verification and validation.

The device has no patient contacting materials and is utilized only by trained professionals. The output of the device is evaluated by trained professionals allowing sufficient review for identification and intervention in the event of a malfunction.

Siemens believes that *syngo*® Dynamics version 9.0 is as safe and effective as its predicate device as it does not introduce new indications for use, raise new

types of safety and effectiveness, or introduce new technology.

8. Conclusion as to Substantial Equivalence

The potential hazards of modifications to the device have been evaluated and controlled as part of the product development process, including risk analysis and design considerations. Siemens conducts testing to verify the design output met the design input requirements and to validate the device conformance to the intended use. Predefined acceptance criteria was met and demonstrated that the device is as safe and effective as the predicate device.

In summary, Siemens is of the opinion that *syngo*® Dynamics 9.0 does not introduce any new significant potential safety risks and is substantially equivalent to and performs as well as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Siemens Medical Solutions, Inc.
% Mr. Norbert Stuiber
Responsible Third Party Official
TÜV SÜD America, Inc.
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

OCT 5 2010

Re: K102150
Trade/Device Name: *syngo*® Dynamics (version 9.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 20, 2010
Received: July 29, 2010

Dear Mr. Stuiber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (If known): _____

Device Name: syngo® Dynamics (version 9.0)

Indications for Use:

syngo® Dynamics is a Picture Archiving and Communication System (PACS) intended for acceptance, transfer, display, storage, archive and manipulation of digital medical images, including quantification and report generation.

syngo® Dynamics is not intended to be used for reading of mammography images.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

David G Brown
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K102150

Page 1 of 1